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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/910,442      07/20/2001      Rajagopal Bakthavatchalam      NCX-003.01      2748

20306      7590      11/07/2002

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EXAMINER
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HABTE, KAHSAY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 11/07/2002

90

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/910,442

Applicant(s)

BAKTHAVATCHALAM ET AL.

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-198 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 7 and 177-192 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-6, 8-176 and 193-198 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

1. Claims 1-198 are pending.

***Election/Restriction***

2. Applicant's election with traverse of Group IV, Claims 4-6 (in part), 8-30, 31 (in part), 32-176 and 193-198 in Paper No. 8 is acknowledged.

It is recommended that applicants delete non-elected inventions in response to this Office Action.

***Information Disclosure Statement***

3. The IDS PTO form 1449 (Paper No.5) was not initialed because the references are missing. The examiner kindly requests applicants to provide the references cited in IDS PTO form 1449 (Paper No. 5).

Note that the IDS PTO form 1449 (Paper No. 9) was initialed.

***Abstract***

4. The abstract is defective because there is no chemical structure that applicants consider as their invention. Applicants have to include chemical structure instead of defining the invention broadly as diaryl piperazines.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-6, 8, 30, 31, and 32-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Cho et al. (WO 98/00402). The cited reference teaches the general preparation of piperazine derivatives, in which phenyl is attached to ring nitrogen of the piperazinyl moiety and phenyl or pyridyl is also attached to the other ring nitrogen via carbonyl or thiocarbonyl containing linker (formula I). Specifically, many of the compounds in Ex. No. 1-231 (pages 9-19) are the same as applicants. For example compound 3: (1-[(5,6-dimethyl-2-methoxypyridin-3-yl)aminocarbonyl]-4-(2,3,5,6-tetramethylphenyl)piperazine) or compound 153 (1-{N-ethyl-N-[5-(1-hydroxyethyl)-2-methoxy-6-methylpyridin-3-yl]aminocarbonyl}4-(3,5-dimethoxyphenyl)piperazine) are the same as applicants.

6. Claims 4-6, 27, 28, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Bock et al. (US Pat. No. 5,756,504). The cited reference teaches the synthesis of 1-(2,4-dimethoxyphenylacetyl)-4-(2-methylphenyl)piperazine (column 31, Example 6) that is the same as applicants.

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7. Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kulagowski et al. (US Pat. No. 5,792,768). The cited reference discloses 1-(2-benzimidazol-2-yl)acetyl-4-phenylpiperazine (column 10, Example 8, line 50) that is the same as applicants.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6, 8-30, 31, 32-176 and 193-198 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 4 or elsewhere in the claim, the term "heterocycloalkyl" is not clear.

Where is the heteroatom? Is it inside the ring or outside the ring? Is it cycloalkyl attached to a heteroatom e.g. -NH-cyclohexyl or is it a heterocycle attached to alkyl e.g. pyridyl-NH-? If applicants intend to claim heterocycle, it is recommended that applicants delete "heterocycloalkyl" from claims and use "heterocycle" instead.

b. Claims 194-196 provides for the use of a compound for the manufacture of a medicament, but, since the claim does not set forth any steps involved in the

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method/process, it is unclear what method/process applicant is intending to encompass.

A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 194-196 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

c. In claim 193, the phrase "the compound or salt is not addictive" is not clear. How can one tell if the salt or the compound is addictive or not? How can one prove that the salt or the compound is not addictive?

### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624



Mark L. Berch  
Primary Examiner  
Art Unit 1624

KH  
October 31, 2002